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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/956,940	09/21/2001	Barton F. Haynes	1579-601	4369

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	11

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/956,940	HAYNES, BARTON F.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-15,19 and 26-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-18,20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election with traverse of Group II and the species protein in Paper No. 9 is acknowledged. The traversal is on the ground(s) that are stated in said paper. This is not found persuasive because of the following reasons. Regarding applicants comments about undue burden, the M.P.E.P. § 803 states that: "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The restriction requirement enunciated in the Office Action mailed 12/3/2002 meets this criterion and therefore establishes that serious burden is placed on the Examiner by the search of additional Groups.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-15,26-31,19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species (claim 19), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

3. Claims 16-18,20-25 are under consideration.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825, however, this application fails to comply with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures. The following procedure is to be used for cases that contain the same sequence disclosure as the parent. The applicant need not submit a new computer readable form of the Sequence Listing for this divisional application. However, (1) the specification must contain a paper copy of the Sequence Listing, (2) applicant must request in writing that the CRF in the parent case be used to prepare a file for the offspring and (3) applicant must submit a statement that the paper copy of the Sequence Listing in the offspring is identical to the computer readable form submitted in the parent case. It is valid to use this approach to bring sequences into divisional or CIPs applications as long as there are no new sequences.

A paper copy of the sequence listing has not been received in the instant application. Applicant also needs to list the appropriate sequence ID no. after any sequence that appears in the specification or claims (eg. claim 25).

Applicant is required to fulfill these requirements.

5. Claim 25 is objected to because the amino acid sequence recited in said claim requires identification with the appropriate SEQ. ID. number. Appropriate correction is required.

6. Applicant needs to update the status of all US Patent applications disclosed in page 1 of the specification.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 18,22-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the method of claim 18. Regarding applicants comments, the method of claim 18 is not disclosed in the originally filed claims or pages 32 and 33 of the specification.

There is no support in the specification as originally filed for the method of claim 22. Regarding applicants comments, the method of claim 22 is not disclosed in the originally filed claims or pages 32 and 33 of the specification. The specification, page 33 discloses use of the method of claim 22 with the additional limitations that the HIV regulatory protein binds viral RNA, but does not promote transcription of RNA thus preventing normal binding of HIV transcription factors and wherein said molecule is used to treat HIV. The method of claim 22 does not recite these limitations and is

therefore broader in scope than the written description provided in the specification as originally filed.

There is no support in the specification as originally filed for the methods of claims 23-25. Said steps are disclosed in original claims 4,5 and 7, however, said claims are not drawn to the claimed method (eg. the steps are recited as part of the method of original claim 1, wherein said method is not the claimed method (eg. it is drawn to a method of inducing immune tolerance to an immunogenic peptide)).

There is no written description in the specification as originally filed of the scope of the claimed inventions (eg. the claimed inventions constitute new matter).

9. Claims 16-18,20-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The instant claims encompass a method that uses any HIV fusion domain to facilitate entry of a molecule into a cells. The specification discloses a single peptide with this function (eg. the peptide disclosed in page 33 of the specification). The claims encompass use of other HIV fusion domains and undisclosed muteins, alleles and variants of said HIV fusion domain. With the exception of the particular HIV derived amino acid sequences disclosed in the specification, the skilled artisan cannot envision the detailed structure of the encompassed peptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. In the instant application, the amino acid itself or isolated protein is required.

See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification discloses a single peptide HIV fusion peptide with the properties recited in the claims (eg. the peptide disclosed in page 33 of the specification) whilst the claims encompass use of other HIV fusion domains and undisclosed muteins, alleles and variants of said HIV fusion domain The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated:

"The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the

sequence of nucleotides that make up the cDNA." See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

10. Regarding priority for the claimed invention and the application of prior art, the claimed invention is not disclosed in parent applications 07/833429, 07/591109 or 07/093854. Therefore, the effective filing date for the claimed invention regarding the application of prior art is that of parent application 08/015987.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 16-18,20,21,23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hart et al.

Hart et al. teach administration of the F-T1-SP10IIIB(A) conjugate peptide to mice (see Table 1). This peptide is the same as disclosed in the specification as an example of a peptide used in the claimed invention (see specification, page 33 and tables 13 and 14). Said peptide contains the fusion domain recited in claim 25 (see Table 1). The fusion domain is conjugated at the c-terminal to a gp120 derived peptide (see Table 1), wherein said peptide is a therapeutic agent . The claimed method encompasses in vivo administration of the conjugate. In view of the fact that Hart et al. discloses in vivo administration of the conjugated recited in the claims, it is an inherent property of said method that it facilitates entry of a molecule into a cell because the prior art method recites the same steps as the claimed method. Furthermore, Hart et al. disclose that CTL generated using their peptide recognize APC processed antigen

(see page 9451, second column, continued on next page). APC processing of antigen requires internalization of the antigen (see page 9451, second paragraph, last two paragraphs).

13. Claims 16-18,20,21,23,24 are rejected under 35 U.S.C. 102(e) as being anticipated by Helting et al. (US Patent 5,204,259).

Helting et al. teach administration of a HIV p24/gp41 fusion protein to a mammal (see column 12, last paragraph and column 13, fourth paragraph). HIV gp41 comprises an HIV fusion domain (see specification, page 5, first paragraph). The fusion domain is conjugated at the n-terminal to HIV p24 wherein said protein is a therapeutic agent. The claimed method encompasses in vivo administration of the conjugate. In view of the fact that Helting et al. discloses in vivo administration of the conjugated recited in the claims, it is an inherent property of said method that it facilitates entry of a molecule into a cell because the prior art method recites the same steps as the claimed method.

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600